Award Number: W81XWH-09-1-0296

TITLE: Vaccination with Dendritic Cell Myeloma Fusions in Conjuction with Stem Cell Transplantation and PD-1 Blockade

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REPORT DATE: July 2015

TYPE OF REPORT: Final Addendum

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
July 2015	Final Addendum	1May2014 - 30Apr2015

4. TITLE AND SUBTITLE
Vaccination with Dendritic Cell Myeloma Fusions in Conjuction with Stem Cell Transplantation and PD-1 Blockade

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-09-1-0296

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Beth Israel Deaconess Medical Center Inc.
Boston, MA 02215-5491

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, MD 21702-5014

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT Choose One of the following:
Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

In this project, we conducted a clinical trial in which patients with multiple myeloma were treated with an anti-PD1 antibody (CT-011) alone (Cohort 1) and in conjunction with a dendritic cell/myeloma fusion cell vaccine (Cohort 2) following autologous transplantation. The goal of the project was to determine the effect of CT-011 alone, and in conjunction with a DC/myeloma fusion cell vaccine, to stimulate effective anti-tumor immunity and disease response.

15. SUBJECT TERMS
Nothing listed

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRMC
U	U	U	UU	25	**19b. TELEPHONE NUMBER** *(include area code)*

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A. INTRODUCTION

In this project, we conducted a clinical trial in which patients with multiple myeloma were treated with an anti-PD1 antibody (CT-011) alone (Cohort 1) and in conjunction with a dendritic cell/myeloma fusion cell vaccine (Cohort 2) following autologous transplantation. The goal of the project was to determine the effect of CT-011 alone, and in conjunction with a DC/myeloma fusion cell vaccine, to stimulate effective anti-tumor immunity and disease response.

B. BODY

Clinical Trial

The study is being conducted in two stages. In the first stage, a pilot study was conducted in which patients were treated with CT-011 alone following autologous transplant. The primary objective of this stage was to explore immunologic responses to CT-011 in the post-transplant period. The secondary objective was to assess the toxicity of treating patients with CT-011 in the post-transplant setting.

In the second stage, patients receive a combination of CT-011 and DC/myeloma fusion vaccination. The primary objective is to determine if cellular immunity is induced by treatment with monoclonal antibody CT-011 and DC/myeloma fusion cells in conjunction with stem cell transplant. The secondary objectives of this stage are: 1) To assess the toxicity associated with treating multiple myeloma patients with monoclonal antibody CT-O11 in combination with DC/myeloma fusion vaccine following autologous transplant, 2) To correlate levels of circulating activated and regulatory T cells with immunologic response, and 3) To define anti-tumor effects using serum markers, radiological studies, and time to disease progression.

Status: The protocol (DF-HCC protocol number 09-061) was open to accrual at the DF/HCC as of March 19, 2010. Rambam Medical Center (RMC) in Haifa, Israel was added on April 26, 2011. Chaim Sheba Medical Center (CHSH) in Tel Hashomer, Israel was added on January 14, 2014. As of May 1, 2014, 64 patients have been screened. There have been eight screen failures:

five patients did not meet eligibility criteria and three patients elected to pursue only standard of care therapy. To date, 62 participants have met eligibility criteria and have been enrolled: 27 patients on the first cohort (19 at DF/HCC and 8 at RMC) and 31 patients on the second cohort (28 at DF/HCC, 5 at RMC, and 2 at CHSH.)

A total of 19 participants have come off study prior to initiating study treatment, as summarized in Table 1. Twelve participants were removed from Cohort 1 (10 at DF/HCC and 2 at RMC) and eight participants were removed from Cohort 2 (7 at DF/HCC and 1 at RMC.)

All participants enrolled onto the first cohort at both DF/HCC and RMC have completed treatment and active follow-up and are now in long-term follow-up.

Of the subjects enrolled onto the second cohort at DF/HCC, twelve have completed treatment and active follow-up, one has completed treatment and is now in active follow-up, five are currently receiving treatment, two have undergone both tumor collection and dendritic cell collection, and are completing induction chemotherapy, and one has undergone tumor collection but not dendritic cell collection, and is receiving induction chemotherapy

Of the subjects enrolled onto the second cohort at RMC and CHSH, two are currently post-transplant and preparing for immunotherapy, three are currently receiving treatment, one has received transplant and is preparing to move forward with post-transplant immunotherapy, and one has undergone both tumor collection and dendritic cell collection, and is completing induction chemotherapy

Subject Study Information

Table 1: Patients Removed from Cohorts 1 and 2 Prior to Initiating Treatment

Subject Initials	Site	Enrollment Number	Cohort	Registration Date	Age	Gender	Race/ Ethnicity	Off -Study Date	Reason Off-Study
LC	DF/HCC	1	1	5/13/2010	48	M	White	8/14/2010	Disease Progression
RG	DF/HCC	2	1	7/2/2010	70	M	White	11/5/2010	Death
DW	DF/HCC	6	1	1/7/2011	47	M	White	10/12/2011	Elected to pursue SOC therapy
GF	DF/HCC	8	1	1/28/2011	73	F	White	10/19/2011	Elected to pursue SOC therapy

Subject Initials	Site	Enrollment Number	Cohort	Registration Date	Age	Gender	Race/ Ethnicity	Off -Study Date	Reason Off-Study
AG	DF/HCC	11	1	6/6/2011	45	F	White	9/25/2012	Patient ineligible to receive treatment
KI	RMC	12	1	6/14/2011	61	M	White	11/6/2011	Elected to pursue SOC therapy
RB	DF/HCC	14	1	8/26/2011	58	M	White	3/1/2012	Elected to pursue SOC therapy
ES	DF/HCC	17	1	11/10/2011	55	F	White	6/21/2012	Elected to pursue SOC therapy
KM (Male)	DF/HCC	18	1	11/10/2011	49	M	Black	1/19/2012	Death
NP	DF/HCC	21	1	12/21/2011	62	F	White	8/10/2012	Patient did not want transplant
IC	DF/HCC	25	1	2/17/2012	66	F	Hispanic	11/26/2013	Patient ineligible due to ongoing infection
HH	RMC	27	1	6/21/2012	30	M	White	11/27/2013	Elected to pursue SOC therapy
PLL	DF/HCC	30	2	10/18/2012	66	M	White	3/21/2013	Elected to pursue SOC therapy
FH	DF/HCC	31	2	11/1/2012	66	M	White	7/29/2014	Death
JG	DF/HCC	36	2	1/4/2013	70	F	White	9/920/13	Elected to pursue SOC therapy
SS	RMC	42	2	3/25/2013	69	M	White	9/24/2013	Elected to pursue SOC therapy
JC	DF/HCC	46	2	5/31/2013	71	M	Black	10/15/2013	Patient not receiving transplant
DD	DF/HCC	48	2	9/19/2013	65	M	White	11/13/2014	Patient not receiving transplant
TH	DF/HCC	54	2	2/24/2014	42	M	White	5/7/2014	Elected to pursue SOC therapy

Summary of Cohort 1 (CT-011 Alone)

Treatment Status:

DF/HCC:

- Ten patients have completed study treatment

RMC:

- Seven patients have completed study treatment

Table 2: Patients Treated with CT-011 Alone

Subject Initials	Site	Enrollment Number	Registration Date	Age	Gender	Race/ Ethnicity	Off -Study Date	Reason Off-Study
RP	DF/HCC	3	7/9/2010	52	F	Black	N/A	N/A
CC	DF/HCC	4	9/29/2010	55	M	White	12/12/2011	Disease Progression
KF	DF/HCC	5	12/30/2010	55	F	White	8/6/13	Disease Progression
DF	DF/HCC	7	1/13/2011	63	M	White	7/11/13	Disease Progression
SM	DF/HCC	9	2/15/2011	58	M	White	N/A	N/A
RR	DF/HCC	10	5/18/2011	67	M	White	N/A	N/A
BF	RMC	13	7/21/2011	64	F	White	1/14/2013	Disease Progression
SMM	RMC	15	9/12/2011	55	M	White	9/24/13	Disease Progression
FM	DF/HCC	16	10/26/2011	50	M	Hispanic	6/14/14	Disease Progression
KM (Female)	DF/HCC	19	11/21/2011	56	F	White	3/15/13	Disease Progression
KR	RMC	20	11/30/2011	47	M	White	12/20/12	Disease Progression
TR	RMC	22	1/9/2012	66	F	White	5/8/13	Disease Progression
BB	DF/HCC	23	1/30/2012	60	M	White	N/A	N/A
TB	RMC	24	2/3/2012	60	M	White	N/A	N/A
LY	RMC	26	5/8/2012	64	M	White	N/A	N/A
SA	RMC	38	2/7/2013	47	F	White	N/A	N/A
JS	DF/HCC	44	5/9/2013	62	F	White	N/A	N/A

Clinical Response:

In total, 17 participants have initiated treatment with CT-011 alone (15 on cohort one and 2 who were enrolled to cohort 2 but did not receive vaccine) and are evaluable for response. Of these 17 participants, 8 remain without disease progression: five participants have achieved a CR and three participants have achieved a VGPR. In addition, 9 participants developed progressive disease and were subsequently removed from study. The median time without disease progression for the 17 evaluable participants is 22 months from transplant.

Table 3: Adverse Events for CT-011 Alone

Subject ID	AE	Start Date	CTC Grade	Relationship to CT-011	Action Taken Regarding TX	Outcome
PM03	Leukopenia	3/14/2011	1	Possible	None	Resolved
PM03	Leukopenia	5/2/2011	1	Possible	None	Resolved
PM03	Leukopenia	5/23/2011	1	Possible	None	Resolved
PM03	Leukopenia	7/11/2011	2	Possible	None	Resolved
PM03	Leukopenia	7/13/2011	1	Possible	None	Resolved
PM03	ANC	5/9/2011	1	Possible	None	Resolved
PM03	ANC	5/23/2011	1	Possible	None	Resolved
PM03	ANC	6/10/2011	2	Possible	None	Resolved
PM03	ANC	7/11/2011	3*	Possible	None	Resolved
PM03	ANC	7/13/2011	1	Possible	None	Resolved
PM03	ANC	9/2/2011	2	Possible	None	Resolved
PM03	ANC	9/30/2011	1	Possible	None	Resolved
PM03	Allergic Rhinitis	7/11/2011	1	Possible	None	Resolved
PM04	Diarrhea	5/5/2011	1	Probable	None	Resolved
PM04	Diarrhea	7/27/2011	1	Possible	None	Resolved
PM04	Diarrhea	9/5/2011	1	Possible	None	Resolved
PM04	Pain, Joint	8/27/2011	2	Possible	None	Resolved
PM04	Night Sweats	9/3/2011	1	Possible	None	Resolved
PM04	Fatigue	8/27/2011	2	Possible	None	Resolved
PM04	Fatigue	9/18/2011	1	Possible	None	Resolved
PM05	Diarrhea	7/7/2011	1	Possible	None	Resolved
PM05	Diarrhea	7/31/2011	1	Possible	None	Resolved
PM05	Diarrhea	9/27/2011	1	Possible	None	Resolved

PM05	Diarrhea	10/19/2011	1	Possible	None	Resolved
PM07	Diarrhea	3/6/2012	1	Possible	None	Resolved
PM09	Diarrhea	10/10/2011	1	Possible	None	Resolved
PM09	Eosinophils, Elevated	12/12/2011	1	Possible	None	Resolved
PM09	Rash (eczema)	10/1/2011	2	Possible	None	Resolved
PM09	Thyroid Function, Low	10/31/2011	1	Possible	None	Resolved
PM10	Arthralgia, hands	6/1/2012	1	Possible	None	Resolved
PM10	Diarrhea	2/2/2012	1	Probable	None	Resolved
PM10	Diarrhea	2/13/2012	1	Possible	None	Resolved
PM10	Diarrhea	2/23/2012	1	Probable	None	Resolved
PM10	Diarrhea	4/27/2012	1	Probable	None	Resolved
PM10	Leukopenia	5/8/2012	1	Possible	None	Resolved
PM10	Nausea	2/1/2012	1	Probable	None	Resolved
PM10	Thyroid Function, Low	3/13/2012	1	Possible	None	Resolved
PM19	Leukopenia	6/4/2012	1	Possible	None	Resolved
PM19	Leukopenia	7/2/2012	1	Possible	None	Resolved
PM19	Leukopenia	7/23/2012	1	Possible	None	Resolved
PM19	Leukopenia	9/4/2012	1	Possible	None	Resolved
PM19	Diarrhea	7/15/2012	1	Possible	None	Resolved
PM19	Diarrhea (intermittent)	8/14/2012	1	Possible	None	Resolved
PM19	Diarrhea (intermittent)	11/2012	1	Possible	None	Resolved
PM19	Lymphopenia	7/23/2012	2	Possible	None	Resolved
PM19	Arthralgia, hands	11/2012	1	Possible	None	Resolved
PM23	Hypothyroidism	10/9/13	1	Possible	None	Resolved
PM44	Arthralgia	3/1/2014	1	Possible	None	Resolved

Treatment Related Serious Adverse Events:

There have been no treatment-related serious adverse events on Cohort 1.

Treatment Summary of Subjects that Died While on Study:

There have been two unrelated deaths on study, both on Cohort 1. The participants had not initiated study treatment. One participant died on 11/5/10 after suffering a cardiac arrest in his home; the event was reported to the Dana Farber Harvard Cancer Center IRB on 11/11/10. Another participant committed suicide on 1/19/12; the event was reported to the Dana Farber Harvard Cancer Center IRB on 1/20/12.

Summary of Cohort 2 (CT-011 + Vaccine)

Treatment Status:

DF/HCC

- Eighteen have received treatment with at least two doses of vaccine + two doses of CT-011
- None are currently receiving treatment
- Three have undergone both tumor collection and dendritic cell collection, and are completing induction chemotherapy
- One has undergone tumor collection but not dendritic cell collection, and is receiving induction chemotherapy

RMC

- Three have received treatment with at least two doses of vaccine + two doses of CT-011
- One is currently receiving treatment
- One has undergone both tumor collection and dendritic cell collection, and is completing induction chemotherapy

Table 4: Patients Treated or Pending Treatment with CT-011 and Vaccine

Patient Initials	Location	Enrollment Number	Registration Date	Age	Gender	Race	Off - Study Date	Reason Off-Study
CG	DF/HCC	28	7/23/2012	61	F	White	N/A	N/A
SF	DF/HCC	29	8/7/2012	48	M	White	1/20/15	Progressive Disease
WP	DF/HCC	32	12/11/2012	63	M	White	12/12/14	Progressive Disease
EH	DF/HCC	33	12/13/2012	68	F	White	12/2014	Progressive Disease
AW	DF/HCC	34	12/17/2012	53	F	White	N/A	N/A
MS	DF/HCC	35	12/21/2012	68	M	White	4/21/15	Progressive Disease
HB	DF/HCC	37	2/7/2013	75	M	White	4/1/15	Progressive Disease
MAG	DF/HCC	39	2/12/2013	66	F	White	N/A	N/A
DP	DF/HCC	40	3/7/2013	71	F	White	N/A	N/A
DH	DF/HCC	41	3/21/2013	59	M	White	N/A	N/A
CK	DF/HCC	43	4/26/2013	49	F	White	7/10/14	Progressive Disease
MB	DF/HCC	45	5/20/2013	52	M	White	3/2/15	To Receive other treatment, no PD
BT	DF/HCC	47	6/21/2013	61	M	White	N/A	N/A
JR	DF/HCC	49	11/25/2013	75	M	African American	3/25/15	Other complicating disease
PE	DF/HCC	50	12/2/2013	67	M	Other	N/A	N/A
EZ	RMC	51	1/20/2014	57	M	White	N/A	N/A
JZ	DF/HCC	52	1/30/2014	48	M	White	N/A	N/A
AT	RMC	53	2/15/2014	48	M	White	N/A	N/A
DZ	CHSH	55	2/26/2014	49	M	White	N/A	N/A
RE	CHSH	56	3/7/2014	51	F	White	N/A	N/A
EP	DF/HCC	57	4/8/2014	57	F	White	3/16/15	Other treatment
RL	DF/HCC	58	4/29/2014	68	M	White	N/A	N/A
MC	DF/HCC	59	5/20/2014	51	M	White	N/A	N/A
IS	RMC	60	5/27/2014	55	F	White	N/A	N/A
PD	DF/HCC	61	5/28/2014	66	M	White	N/A	N/A
JB	DF/HCC	62	5/29/2014	69	M	White	N/A	N/A

Clinical Response: At this time, 22 patients have received treatment on study and are evaluable, as summarized below in Table 5.

Table 5: Patients Treated with CT-011 and Vaccine

CG/PM28	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1. 5/9/13 Inf #1. 5/16/13 Vac #2. 6/20/13 Inf #2. 6/27/13 Vac #3. 8/8/13 Inf #3. 8/15/13	Best response at the end of transplant was a very good partial response. Since completing treatment, the participant has remained in a very good partial response.
SF/PM29	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1. 3/7/13 Inf #1. 3/14/13 Vac #2. 4/18/13 Inf #2. 4/25/13 Vac #3. 5/30/13 Inf #3. 6/6/13	Best response at the end of transplant was complete response. The participant developed progressive disease 24.5 months from transplant and was removed from the study.
WP/PM32	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1. 7/29/13 Inf #1. 8/5/13 Vac #2. 9/9/13 Inf #2. 9/16/13 Vac #3.10/21/13 Inf #3. 10/28/13	Best response at the end of transplant was a very good partial response. The participant developed progressive disease 18.9 months from transplant and was removed from the study.
EH/PM33	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1. 6/4/13 Inf #1. 6/11/13 Vac #2. 7/16/13 Inf #2. 7/23/13 Vac #3. 8/27/13 Inf #3. 9/3/13	Best response at the end of transplant was complete response. The participant experienced progressive disease 19.5 months from transplant and was removed from the study.
AW/PM34	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1. 7/16/13 Inf #1. 7/23/13 Vac #2. 9/3/13 Inf #2. 9/10/13 Vac #3 10/15/13 Inf #3. 10/22/13	Best response at the end of transplant was a complete response. Since completing treatment, the participant has remained in a complete response.
MS/PM34	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1. 8/6/13 Inf #1. 8/13/13 Vac #2. 9/17/13 Inf #2. 9/24/13	Best response at the end of transplant was a partial response. The participant experienced progressive disease 22 months from transplant and was removed from the study.
HB/PM38	Cohort 2: CT-011 3 doses at 3mg/kg (did not generate enough cells for vaccine)	Vac #1. 9/24/13 Inf #1. 10/1/13 Vac #2. 1/30/14 Inf #2. 2/13/14 Vac #3 3/20/14 Inf #3. 3/27/14	Best response at the end of transplant was a very good partial response. Since completing treatment, the participant developed progressive disease 12.6 months from transplant and was removed from the study.
MAG/PM39	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1. 9/24/13 Inf #1. 10/1/13 Vac #2. 11/5/13 Inf #2. 11/12/13 Vac #3 12/17/13 Inf #3. 12/26/13	Best response at the end of transplant was a very good partial response. Since completing treatment, the participant has remained in a very good partial response.

DP/PM40	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1. 11/21/13 Inf #1. 11/29/13 Vac #2. 1/9/14 Inf #2. 1/16/14 Vac #3 2/19/14 Inf #3. 2/27/14	Best response at the end of transplant was a very good partial response. Since completing treatment, the participant has remained in a very good partial response.
DH/PM41	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1 4/3/14 Inf # 1 4/9/14 Vac #2 5/29/14 Inf #2 6/5/14 Vac #3 7/10/14 Inf #3 7/17/14	Best response at the end of transplant was a very good partial response. Since completing treatment, the participant's response has transformed to a CR, 8 months from transplant and 3 months following completion of study treatment.
CK/PM43	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1 2/11/14 Inf #1 3/7/14 Vac #2 4/8/14 Inf #2 4/16/14 Vac #3 5/21/14 Inf #3 6/2/14	Best response at the end of transplant was a partial response. The participant experienced progressive disease 6.6 months from transplant and was removed from the study.
MB/PM45	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1 2/11/14 Inf #1 2/27/14 Vac #2 4/1/14 Inf #2 4/10/14 Vac #3 5/13/14 Inf #3 5/22/14	Best response at the end of transplant was a near complete response. Since completing treatment, the participant's response has transformed to a CR, 5 months from transplant during the second cycle of study treatment. He opted to start maintenance lenalidomide 16 months from transplant and was removed from study without progressing.
BT/PM47	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1 2/14/14 Inf #1 2/20/14 Vac #2 4/1/14 Inf #2 4/8/14 Vac #3 5/15/14 Inf #3 5/20/14	Best response at the end of transplant was a very good partial response. Since completing treatment the participant has remained in a very good partial response.
JR/PM49	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1 12/12/14 Inf #1 12/19/14 Vac #2 1/20/15 Inf #2 1/29/15 Vac #3Not given Inf #3 Not given	Best response at the end of transplant was a very good partial response. The participant was removed from treatment due to an adverse event prior to receiving his third vaccine.
PE/PM50	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1 11/6/14 Inf #1 11/18/14 Vac #2 12/23/14 Inf #2 12/29/14 Vac #3 2/23/15 Inf #3 3/3/15	Best response at the end of transplant was a very good partial response. Since completing treatment the participant has remained in a very good partial response
ZE/PM51	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1 11/18/14 Inf #1. 11/26/14 Vac #2 1/4/15 Inf #2. 1/8/15 Vac #3 2/10/15 Inf #3. 2/19/15	Best response at the end of transplant was PR. Since completing treatment the participant has remained in partial response
JZ/PM52	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1 9/4/14 Inf #1 9/11/14 Vac#2 10/14/14 Inf #2 10/21/14 Vac#3 12/04/14 Inf #3 12/11/14	Best response at the end of transplant was a near complete response. Since completing treatment, the participant's response has transformed to a CR, 1 month following his last infusion.

TA/PM53	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1 12/9/14 Inf #1 12/17/14 Vac #2 1/21/15 Inf #2 1/28/15 Vac #3 3/4/15 Inf #3 3/11/15	Best response at the end of transplant was PR. Since completing treatment the participant has remained in partial response
ZD/PM55	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1 12/16/14 Inf #1 12/23/14 Vac #2 1/27/15 Inf #2. 2/3/15 Vac #3 3/10/15 Inf #3. 3/18/15	Best response at the end of transplant was CR. Since completing treatment the participant has remained in complete response.
EP/PM57	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1 12/15/14 Inf #1 12/23/14 Vac #2 1/29/15 Inf #2 2/6/15 Vac #3 3/9/15 Inf #3 Not given	Best response at the end of transplant was a partial response. The participant will have her disease reassessed at one month following completion of treatment.
SI/PM60	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1 2/18/15 Inf #1. 2/25/15 Vac #2 4/1/15 Inf #2. 4/6/15 Vac #3 not given Inf #3. 5/21/15	Best response at the end of transplant was PR. Since completing treatment the participant has remained in partial response
PD/PM61	Cohort 2: DC/MM Fusion Vaccine 3 doses at 5x10^6 cells + CT-011 3 doses at 3mg/kg	Vac #1 1/29/15 Inf #1 2/5/15 Vac #2 3/12/15 Inf #2 3/20/15 Vac #3 4/30/15 Inf #3 5/7/15	Best response at the end of transplant was a complete response. The participant will have his disease reassessed at one month following completion of treatment.

Table 6: Related Adverse Events for CT-011 and Vaccine

Subject ID	AE	Start Date	CTC Grade	Relationship to CT-011	Relationship to Vaccine	Action Taken Regarding TX	Outcome
PM29	Myalgias	3/7/2013	1	Unrelated	Possible	None	Resolved
PM29	Arthralgia, R ankle	3/11/2013	1	Unrelated	Possible	None	Resolved
PM29	Vaccine Site Reaction	3/11/2013	1	Unrelated	Definitely	None	Resolved
PM29	Ecchymosis, vaccine site	3/13/2013	1	Unrelated	Definitely	None	Resolved
PM29	Facial Flushing	3/10/2013	1	Unrelated	Possible	None	Resolved
PM29	ANC	3/14/2013	1	Unrelated	Possible	None	Resolved
PM29	Leukopenia	3/14/2013	1	Unrelated	Possible	None	Resolved
PM29	Flu-like Symptoms	3/14/2013	1	Possible	Unrelated	None	Resolved
PM29	Leukopenia	4/4/2013	1	Possible	Unrelated	None	Resolved
PM29	ANC	4/4/2013	1	Possible	Unrelated	None	Resolved
PM32	Musculoskeletal, other (a brief episode of muscle spasms)	7/29/2013	1	Unrelated	Probable	None	Resolved
PM32	Injection site reaction	7/29/2013	1	Unrelated	Definite (GM-CSF)	Ibuprofen	Resolved
PM32	Pain, joint	8/5/2013	1	Definite	Definite	None	Resolved
PM32	Pain, muscle	8/5/2013	1	Definite	Definite	None	Resolved
PM32	Pain, muscle	9/13/2013	1	Unrelated	Definite (GM-CSF)	None	Resolved
PM32	Pain, joint	9/13/2013	1	Unrelated	Definite (GM-CSF)	None	Resolved
PM32	Injection site reaction	9/14/2013	1	Unrelated	Definite (GM-CSF)	None	Resolved
PM32	Pain, Joint	9/19/2013	1	Probable	Probable	None	Resolved
PM32	Rhinitis	10/23/2013	1	Possibly	Unrelated	None	Resolved
PM32	Diarrhea	10/23/2013	1	Possibly	Unrelated	None	Resolved
PM32	Injection site reaction	10/23/2013	1	Unrelated	Definite	None	Resolved
PM32	Rash, chest/abd	10/28/2013	1	Unrelated	Possibly	None	Resolved
PM32	Rash, chest/abd	11/19/2013	1	Possibly	Possibly	None	Resolved
PM32	Pain, muscle	9/19/2013	1	Probable	Probable	None	Resolved
PM33	Elevated TSH	11/26/2013	1	Possibly	possibly	None	Ongoing
PM34	Injection site reaction	10/17/2013	1	Unrelated	Definite	None	Resolved
PM34	Injection site reaction	9/5/2013	1	Unrelated	Definite (GM-CSF)	None	Resolved
PM35	Neutropenia	10/8/2013	3	Probable	Probable	None	Resolved
PM35	Neutropenia	10/11/2013	4	Probable	Probable	None	Resolved
PM35	Neutropenia	10/15/2013	3	Probable	Probable	None	Resolved

Subject ID	AE	Start Date	CTC Grade	Relationship to CT-011	Relationship to Vaccine	Action Taken Regarding TX	Outcome
PM35	Pain at injection site	8/6/2013	1	Unrelated	Definite (GM-CSF)	None	Resolved
PM35	Injection site reaction	9/21/2013	1	Unrelated	Definite (GM-CSF)	None	Resolved
PM37	Chills (during infusion)	12/26/2013	1	Possibly	Unrelated	None	Resolved
PM37	Injection site reaction	1/31/2014	1	Unrelated	Definite	None	Resolved
PM37	Injection site reaction	2/9/2014	1	Unrelated	Probable	None	Resolved
PM37	Injection site reaction	3/20/2014	1	Unrelated	Definite	None	Resolved
PM37	Thyroid Function, Low	3/20/2014	1	Possibly	possibly	None	Resolved
PM39	Injection site reaction	9/25/2013	1	Unrelated	Definite	None	Resolved
PM39	Diarrhea, Interim	10/2/2013	1	Possibly	Possibly	None	Resolved
PM39	Pain, abd NOS, interim	10/2/2013	1	Possibly	Possibly	None	Resolved
PM39	Pain, back, interm	10/2/2013	1	Possibly	Possibly	None	Resolved
PM39	Leukocytes	10/15/2013	1	Possibly	Unrelated	None	Resolved
PM39	Pain shoulders	10/1/2013	1	Possibly	Unrelated	None	Resolved
PM39	Diarrhea	10/28/2013	1	Possibly	Unrelated	None	Resolved
PM39	Nausea	10/29/2013	1	Possibly	Unrelated	None	Resolved
PM39	Arthralgia	10/1/2013	1	Possibly	Unrelated	None	Resolved
PM39	Diarrhea	11/8/2013	1	Possibly	Unrelated	None	Resolved
PM39	Diarrhea	12/3/2013	1	Possibly	Unrelated	None	Resolved
PM39	Injection site reaction	11/6/2013	1	Unrelated	Definite	None	Resolved
PM39	Rash, upper chest	11/9/2013	1	Possibly	Possibly	None	Resolved
PM39	Rash arm	11/9/2013	1	Possibly	Possibly	None	Resolved
PM39	Leukocytes	11/12/2013	1	Possibly	Possibly	None	Resolved
PM39	Nausea	11/13/2013	1	Possibly	Unrelated	None	Resolved
PM39	Pain, back	12/23/2013	1	Possibly	Possibly	None	Resolved
PM39	Pain, shoulder	12/23/2013	1	Possibly	Possibly	None	Resolved
PM39	Diarrhea	12/18/2013	1	Possibly	Possibly	None	Resolved
PM39	Injection site reaction	12/18/2013	1	Unrelated	Definite	None	Resolved
PM39	Pain back	1/21/2014	1	Possibly	Unrelated	None	Resolved
PM40	Injection site reaction	11/24/2013	1	Unrelated	Definite	None	Resolved
PM40	Pain, b/l thigh	12/1/2013	1	Possibly	Unrelated	None	Resolved
PM40	Diarrhea	1/12/2014	1	Possibly	Possibly	None	Resolved
PM40	Abdominal pain	1/14/2014	1	Possibly	Possibly	None	Resolved
PM40	Nausea	1/13/2014	1	Possibly	Possibly	None	Resolved

Subject ID	AE	Start Date	CTC Grade	Relationship to CT-011	Relationship to Vaccine	Action Taken Regarding TX	Outcome
PM40	Anorexia	1/12/2014	1	Possibly	Possibly	None	Resolved
PM40	Injection site reaction	1/13/2014	1	Unrelated	Possibly	None	Resolved
PM40	Injection site reaction	2/20/2014	1	Unrelated	Possibly	None	Resolved
PM40	Diarrhea	3/2/2014	1	Possibly	Possibly	None	Resolved
PM40	Injection site reaction	3/3/2014	1	Unrelated	Possibly	None	Resolved
PM40	Rash	3/UNK/14	1	Possibly	Possibly	none	Resolved
PM41	Rash (face and scalp)	4/27/2014	2	Possibly	Possibly	None	Resolved
PM41	Rash (face and scalp)	5/8/2014	1	Possibly	Possibly	None	Resolved
PM41	Rash (face and scalp)	5/11/2014	2	Possibly	Possibly	None	Resolved
PM41	Injection site reaction	6/4/2014	1	Unrelated	Possibly	None	Resolved
PM43	Diarrhea	2/13/2014	2	Possibly	Possibly	None	Resolved
PM43	Fatigue	3/8/2014	2	Definite	Unrelated	None	Resolved
PM43	ALT	5/21/2014	1	Possibly	Possibly	None	Resolved
PM43	AST	5/21/2014	1	Possibly	Possibly	None	Resolved
PM43	Fatigue	4/16/2014	1	Probable	Unrelated	None	Resolved
PM45	Injection site reaction	2/11/2014	1	Unrelated	Definite	None	Resolved
PM45	Injection site reaction	4/2/2014	1	Unrelated	Definite	None	Resolved
PM45	Injection site reaction	5/14/2014	1	Unrelated	Definite	None	Resolved
PM45	Injection site reaction	5/17/2014	2	Unrelated	Definite	None	Resolved
PM45	Injection site reaction	5/19/2014	1	Unrelated	Definite	None	Resolved
PM45	Headache	5/14/2014	1	Unrelated	Definite	None	Resolved
PM47	Injection site reaction	5/15/2014	1	Unrelated	Definite	None	Resolved
PM47	Fatigue	5/21/2014	1	Possibly	Unrelated	None	Resolved
PM47	Diarrhea	5/21/2014	1	Probable	Unrelated	None	Resolved
PM51	Redness at the site of vaccination	4.01.15	1	Unrelated	Possibly	None	Resolved
PM52	Injection site reaction	9/7/14	1	Unrelated	Related	None	Resolved
PM52	Diarrhea	9/22/14	1	Possibly	Unrelated	None	Resolved
PM52	Injection site reaction	10/15/14	1	Unrelated	Related	None	Ongoing
PM52	Fatigue	10/22/14	1	Possibly	Unrelated	None	Resolved
PM52	Injection site rxn	12/6/14	1	Unrelated	Related	None	Resolved
PM52	Rash, on back	12/4/14	1	Possibly	Unrelated	None	Resolved

Subject ID	AE	Start Date	CTC Grade	Relationship to CT-011	Relationship to Vaccine	Action Taken Regarding TX	Outcome
PM55	Redness and Induration at the site of vaccination	11.03.2015	1	Unrelated	Possibly	None	Resolved
PM57	Myalgia	12/18/14	2	Unrelated	Possibly	None	Resolved
PM57	Diarrhea	12/19/14	1	Unrelated	Possibly	None	Resolved
PM57	Fatigue	12/31/14	1	Possibly	Unrelated	None	Resolved
PM57	Myalgia	2/7/15	1	Possibly	Unrelated	None	Resolved
PM57	Diarrhea	2/7/15	1	Possibly	Unrelated	None	Resolved
PM57	Injection site rxn	3/9/15	1	Related	Unrelated	None	Resolved
PM57	Myalgia	3/15/15	1	Unrelated	Possibly	None	Resolved
PM61	Injection site rxn	1/31/15	1	Unrelated	Related	None	Resolved
PM61	Diarrhea	2/8/15	1	Probably	Unrelated	None	Resolved
PM61	Rash	3/5/15	1	Unrelated	Possible	None	Resolved
PM61	Injection site rxn	3/15/15	1	Unrelated	Related	None	Resolved
PM61	Injection site rxn	4/30/15	1	Unrelated	Related	None	Resolved

Treatment Related Serious Adverse Events:

There has been one serious adverse event related to study treatment on Cohort 2. On 10/11/13, participant PM35 presented to clinic for week 2 follow-up after his second infusion of CT-011 with grade 4 neutropenia (expected, probably related to CT-011 and vaccine.) The participant received neupogen per protocol. The participant returned again on 10/22/13, at which time his ANC had resolved to normal. The participant remained asymptotic and without infection. Per protocol, the participant was taken off treatment. This met the criteria for a DLT. This was reported to the FDA as S326 on 10/23/13. Unrelated AEs and SAEs are listed in the summary of unrelated adverse events in Table 7.

Potency of Fusion Cells as Antigen Present Cells: DC, tumor and fusion preparations were assessed for the capacity to stimulate allogeneic T cell proliferation. Antigen presenting cells were co-cultured with T cells for approximately 5 days at a 1:10 ratio. Proliferation was determined by uptake of tritiated thymidine after overnight pulsing. Results are presented as the stimulation index as defined by: proliferation of T cells stimulated by the indicated populations/proliferation of unstimulated T cells.

Subjects	Tumor	DCs	Fusions
PM28	1.6	6.2	6.9
PM29	1.2	4.8	4.3
PM32	1.5	14.4	15
PM33	2.6	15.3	13.4
PM34	2.9	27.4	26.7
PM35	0.5	7.5	8.11
PM36	1	12.1	13.9
Mean	1.9	14.6	14.7

Immunological Responses to Date: Immunologic response was determined by quantifying circulating tumor reactive T cells at each time point as defined by the percent T cells expressing IFNg in response to ex vivo exposure to autologous tumor lysate. Results are presented as the percentage of CD4 or CD8 T cells expressing IFNg.

Cohort 1:

Patient ID	IFNg (REN)	Pre-Mobilization	Pre-Infusion 1	Pre-Infusion 2	Pre-Infusion 3	1 Month	3 Month	6 Month
PM03	CD4/IFNg	0.21	0.39	1.23	3.27	1	1.85	3.42
	CD8/IFNg	0.42	3.43	11.33	13.3	3.34	4.61	9.22
PM04	CD4/IFNg	0.27	0.14	4.79	2.82	11	5.97	Not Done
	CD8/IFNg	2.56	1.4	3.32	3.9	10.7	3.37	Not Done
PM05	CD4/IFNg	0.07	0.33	0.39	4.08	3.82	0.19	0.31
	CD8/IFNg	0.49	0.39	1.25	11.99	11.76	1.4	0.49
PM09	CD4/IFNg	0.55	5.2	1.27	2.53	1.2	0.67	0.35
	CD8/IFNg	0.7	2.6	10.63	6.68	7.31	5.1	3.61
PM10	CD4/IFNg	0.23	0.2	0.5	0.17	0.42	0.56	0.52
	CD8/IFNg	2.3	3.2	5.47	0.71	4.2	3.69	4.32
PM16	CD4/IFNg	0.53	0	1.71	Not Done	0	0.2	0
	CD8/IFNg	Not Done	Not Done	0.69	Not Done	Not Done	0.27	0.5
PM19	CD4/IFNg	0.14	3.96	Not Done	Not Done	Not Done	1.97	1.67
	CD8/IFNg	0	Not Done	Not Done	Not Done	Not Done	2.99	1.13

Cohort 2:

Patient ID	IFNg (REN)	Pre-Mobilization	Pre-Vaccine 1	Pre-Vaccine 2	Pre-Vaccine 3	1 Month	3 Month	6 Month
PM28	CD4/IFNg	3.44	0.22	0.13	Not Done	Not Done	Not Done	Not Done
	CD8/IFNg	0.82	0.94	0.37	Not Done	Not Done	Not Done	Not Done
PM29	CD4/IFNg	0.6	1.28	0.27	0.07	0.78	1.15	Not Done
	CD8/IFNg	2.49	2.83	3.19	3.01	1.85	4.11	Not Done
PM32	CD4/IFNg	1.2	0.45	1.06	0.5	1.38	0.13	0.27
	CD8/IFNg	2.75	3.4	5.24	1.58	3.55	1.41	2.06
PM33	CD4/IFNg	0.36	0.67	0.19	1.24	Not Done	1.48	1.8
	CD8/IFNg	1.48	2.68	2.04	5.23	Not Done	4.14	3.88
PM34	CD4/IFNg	1.12	0.2	1.27	0.74	0.23	0.14	0.1
	CD8/IFNg	2.33	3.29	7.85	3.98	2.86	2.37	4.03
PM35	CD4/IFNg	1.42	3.28	6.74	Not Done	5.25	0.87	2.08
	CD8/IFNg	1.78	1.7	5.44	Not Done	4.07	1.01	1.74
PM38	CD4/IFNg	1.33	Not Done	2.14	5.58	0.81	1.33	2.36
	CD8/IFNg	2.39	Not Done	3.02	6.23	1.52	1.68	1.38
PM39	CD4/IFNg	2.46	6.05	0.95	49.27	6.53	5.17	1.64
	CD8/IFNg	1.73	0.76	8.45	29.03	3.64	3.27	1.28
PM40	CD4/IFNg	0.5	0.89	7.78	16.69	2.04	5.92	3.19
	CD8/IFNg	0.87	0.83	6.88	10.6	2.67	5.88	2.13
PM45	CD4/IFNg	0.42	0	0.55	0.27	0.07	0.1	0.29
	CD8/IFNg	1.35	0	1.82	2.56	2.46	4.89	1.52

C. REPORTABLE OUTCOMES

There are no updated reportable outcomes since last year.

D. KEY RESEARCH ACCOMPLISHMENTS

Based on the results of this research a phase II randomized trial of this cancer vaccine will be conducted through the oncology cooperative group sponsored by the National Heart Lung and Blood Institute at the NIH.

E. CONCLUSIONS

Autologous stem cell transplantation (ASCT) for multiple myeloma (MM) offers a unique setting to incorporate immunotherapy in an effort to target residual disease. Our group has developed a cancer vaccine in which dendritic cells (DCs) are fused to autologous tumor cells resulting in the presentation of multiple tumor antigens with the capacity to elicit a broad anti-tumor response. A fundamental challenge to developing a more effective tumor vaccine is overcoming the immunosuppressive milieu by which tumor cells evade host immunity. Upregulation of the PD-1/PDL1 pathway represents a key element contributing to tumor-mediated tolerance, and potentially muting response to vaccination. We are conducting a clinical trial in which patients with MM are treated with an anti-PD1 antibody (CT-011) alone (cohort 1) and in combination with a dendritic cell/myeloma fusion cell vaccine (cohort 2) following autologous transplantation. 39 patients have been treated with post-transplant immunotherapy (17 in cohort 1; 22 in cohort 2). Mean age was 64 (39 male; 23 female). MM cells were isolated from bone marrow and were identified by expression of CD38 or CD138. Mean tumor cell yield was $118x10^6$ cells. Adherent mononuclear cells were isolated from leukapheresis collections and cultured with GM-CSF and IL-4 for 5-7 days, then exposed to TNFα for 48-72 hours to generate

mature DCs. DCs expressed co-stimulatory (mean CD86 75%) and maturation markers (mean CD83 50%). DC and MM cells were co-cultured with PEG and fusion cells were quantified by determining the percentage of cells that co-express unique DC and myeloma antigens. Mean fusion efficiency was 41% and the mean cell dose generated was 4×10^6 fusion cells. Mean viability of the DC, myeloma, and fusion preparations was 92%, 89%, and 85%, respectively. As a measure of their potency as antigen presenting cells, DC/MM fusions potently stimulate allogeneic T cell proliferation ex-vivo (Mean stimulation index of 1.9, 9.2 and 7.1 for tumor, DC and DC/myeloma fusions respectively, n=21) Post-transplant immunotherapy was initiated after recovery from transplant-related toxicities. Median time from transplant to initiation of post-transplant immunotherapy was 80 days. Patients in cohort 1 received 3 doses of CT-011 at 6-week intervals; in cohort 2, DC/myeloma fusion cells vaccination is administered 1 week before each dose of CT-011. To date, 17 completed CT-011 in cohort 1, and 22 patients in cohort 2 have completed vaccinations and CT-011. Adverse events judged to be potentially treatment related included grade 1-2 diarrhea, arthralgias, myalgias, fatigue, headache, nausea, chills, transaminitis, cytopenia, elevated TSH, and vaccine site reactions. 3 episdoes of grade 3-4 neutropenia were self-limited and not associated with infection. A significant increase in circulating tumor reactive lymphocytes was noted following post-transplant immunotherapy, as determined by T cell expression of IFN-γ by CD8 cells following *ex-vivo* co-culture with autologous myeloma cell lysate (Mean percentage of tumor reactive CD8 cells increased from 1.16% and 1.8% post-transplant to a peak of 7.96% and 9.16% following immunotherapy in cohorts 1 and 2 respectively. In a subset of HLA2.1+ patients, expansion of antigen specific T cells was demonstrated by a 3.8 fold expansion on circulating MUC1+ tetramer+ cells in response to vaccination. In the post-transplant period, regulatory T cells fell to minimal levels

and remained low throughout the period of immunotherapy. 9 patients achieved a best response of VGPR (3 patients in cohort 1, 6 patients in cohort 2). 11 patients have achieved an nCR/CR (5 patients in cohort 1; 6 patients in cohort 2, including 3 who converted to CR following immunotherapy). Median PFS from transplant for cohorts 1 and 2 are 25 months and 19 months respectively.

In summary, DC/MM fusion cell vaccination in conjunction with PD1 blockade following ASCT was well tolerated, potently induced anti-tumor immunity, and in a subset of patients, resulted in the eradication of post-transplant residual disease. Patients continue to be followed for durable clinical response and data analysis is ongoing. Future plans involve a first of its kind national, phase II study conducted through the oncology cooperative group sponsored by the National Heart Lung and Blood Institute at the NIH. The study will look at this vaccine in combination with lenalidomide vs lenalidomide alone in the post-transplant setting and will be conducted in 15 leading cancer centers throughout the United States with an integrated scientific assessment of immunologic response. We are also conducting a phase II study of fusion vaccination in patients achieving remission with acute myeloid leukemia in which preliminary results demonstrate durable remissions in nearly 75% of patients 3 years following completion of vaccination. Finally, we will be exploring pre-clinically and clinical trials the incorporation of other immune modulatory agents such as checkpoint blockade with vaccine therapy.

E. BIBLIOGRAPHY

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F. PERSONNEL

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